HHS/FDA

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September 25, 2000.

President Bill Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500.

Dear President Clinton: Re: H.R. 4461/S. 2536. FDA Labeling Requirements for Irradiated Foods.

I am writing to oppose any attempt to change or weaken the current FDA labeling requirements for irradiated foods. I have read that the USDA/FDA appropriations bill cited above contains a section requiring the FDA to develop "alternative terms" for describing irradiated foods, for example cold pasteurization; this would be an oxymoron when one considers that pasteurization requires heating. Such terms would deceive consumers who are rightfully apprehensive about irradiated foods.

I am writing to urge you to remove all labeling instructions from the final appropriations bill coming out of the conference committee, and allow the current FDA labeling requirements for irradiated food stand as they are. The consumer needs truthful labels to protect himself from potentially harmful substances. I have discussed the formation of carcinogens and mutagens in foods during irradiation in the enclosed review written for the journal "Nutrition". I showed, for example, that irradiation of only 30 milligrams of sugar (1/250 teaspoon) produces one mutagenic dose of formaldehyde as determined by the Ames test. There is much additional evidence for carcinogen production during irradiation that is discussed. The production of clinical cancer by a carcinogenic insult takes decades: Consider that people begin smoking in their teens but do not develop lung cancer until age 50 and over. Since increasing carcinogen exposure by food irradiation will inevitably increase cancer incidence, unambiguous labeling is essential to allow consumers to make appropriate choices. Individuals with a life expectancy of three or more decades have a right to information that will protect them from this insidious assault on their well being. Irradiation at the FDA-approved dose kills 90-99% of bacteria. Irradiation will therefore not sterilize the food but merely delay the onset of symptoms without affecting severity or duration of disease: The surviving bacteria will divide about every 20 minutes in our intestines and thus amplify their number one-million fold overnight. This delay of symptoms will make it more difficult to determine the origin of the bacteria and is of no benefit to the consumer. The only benefit of irradiation is to the food business in extending shelf life and showing that industry is trying to do something that is touted as a consumer benefit. Should not the risk be borne by the same individual who potentially benefits from irradiation?

Any change in the current truthful labeling of irradiated food can only be seen by consumers as an accommodation to business interests at consumer expense. Many voters already suspect that money influences votes. Please, do not give us cause to suspect this in this situation!

I would appreciate it very much if you would let me know what action you plan in response to this letter.

Sincerely,

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Food Irradiation

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In 1986, at a reunion of the Rockefeller University Hospital alumni, I was chatting with Lewis Thomas, then CEO of Sloan Kettering Cancer Institute. He invited me to join a group of scientists, the Media Resource Service of the Scientists' Institute for Medical Information, who were willing to provide the press with explanations and comments on scientific matters. This has resulted in my being invited to discuss possible relations between food irradiation and cancer before the Waxman Committee of the US Congress, and before legislative committees of the states of New York, New Jersey, and Hawaii. I have also participated in discussions with newspaper and television journalists and with food technology departments at Cornell University and the State University of New York at Buffalo. My comments are based on 45 y of experience since my doctorate at Cornell Medical College, Rockefeller University, and since 1959, at Roswell Park Cancer Institute, and are my own; they do not reflect official positions of the New York State Department of Health or the State University of New York at Buffalo.

At this point I should state that my comments and testimony have been that irradiation produces mutagenic and carcinogenic compounds in food, and that the testing design for irradiated food safety has been inadequate to detect carcinogenicity in humans. The most lethal food contaminants, the spores of *Clostridium botulinum* and the entity causing bovine spongiform encephalopathy (mad cow disease) are resistant to the permitted doses of radiation.

Because my arguments will not be accompanied by those of a proponent of food irradiation, I will attempt, with all the honesty and integrity at my command, to allude to both sides of this polemic, although, admittedly, probably with unequal intensity. Food irradiation is not just a scientific issue. The economic considerations are appreciable. It was stated in 1995,[1] before US Food and Drug Administration (FDA) approval of food irradiation, that "Economic analysis shows that the public health benefits expected from the reduced number and severity of food-borne illness resulting from use of irradiation are greater than the costs associated with implementation of the irradiation process." I will not address economic issues in this paper.

Irradiation has been proposed to control food contamination by microorganisms, *Escherichia coli* 0157:H7 among others, which have produced serious morbidity and even mortality during several outbreaks across the United States during the last two decades. With *E. coli* 0157:H7 it is evident that these bacteria, which normally inhabit the intestines of a small percentage of cattle, contaminate the meat as a result of puncture of the intestines during the slaughtering process.

Irradiation at the FDA-approved dose of 100 krad kills 90–99% of most organisms. The food is not sterilized by this dose. Higher doses would adversely alter the organoleptic acceptability of the food. Irradiation will extend the shelf life of the food appreciably, perhaps doubling it, but by no means indefinitely. The few percent of the remaining contaminating organisms will continue to divide during storage, and eventually the food will be "spoiled." Analyses of a *Salmonella* outbreak traced to contaminated cheese revealed that as little as one organism per 300 g of cheese sufficed to infect an individual.[2] In a published study of irradiated fish fillets,[3] the increase in the number of bacteria produced during cold storage of the irradiated and unirradiated fillets was tabulated. It is clear that bacteria can divide after irradiation, and can reach the same population levels after an extended time of storage as the unirradiated cells. In this instance, the storage time was increased by an additional 14 days until bacterial contamination equaled that of the unirradiated fillets. We analyzed these bacterial growth rates by fitting linear and exponential relations to the tabulated data of numbers of bacteria versus time; see Table 1 for these data.

From these curve fittings, it is evident that bacteria in the irradiated fillets reproduced exponentially, whereas those in unirradiated fillets increased in a linear relation with time. Exponential growth results when cells divide and all progeny divide further. Linear growth results when only a fraction of the progeny divide. Thus, although irradiation lowers the bacterial contamination significantly, the surviving bacteria are able to divide to produce progeny. Hence, a new population of bacteria has been selected, which is of course, by definition, more radiation resistant than the population from which it was derived. It is not known whether this new population differs in other regards from the original population; the FDA has not investigated this aspect of the irradiation process. This is brought up because it has been stated[4] that the survivors of irradiation have been so-called "weakened," but no further details were given. Recently, the most radiation-resistant organism known, *Deinococcus radiourans,* was isolated from irradiated canned meat.[5] The polyploid nature of this organism, with logarithmically growing cells containing 4 to 10 genome equivalents, is an important component of its highly efficient DNA repair system.

Exponentially dividing cells will amplify the cell population so that 20 cell divisions will produce one million progeny from each surviving cell. *E. coli* 0157:H7 divide rapidly, about every 20 min, so that about 7 h in a favorable environment such as the gastrointestinal tract will provide a million-fold increase in cell number. Thus, irradiation will not eliminate morbidity related to bacterial contamination, but delay the onset of symptoms, provided of course that the pathologic properties of the radiation-resistant survivors remains unaltered and are not weakened. This delay would make it more difficult to trace the origin of the contamination, and thus provides a dubious benefit to consumers. The definitive test of this reasoning requires an experiment in a real-life setting, a proposal of questionable ethical implications. During testimony before a New York State legislative committee considering legalization of food irradiation, a representative interrupted my presentation with the following insightful observation. At the time when food in grocery stores is near its "expiration date," before it is considered spoiled, the price must be lowered drastically so that the food is sold quickly before overt spoilage. This would attract the poorer members of our society, making them the unwitting experimental subjects for field-testing the safety of irradiated food. In a democracy, this must be abhorrent to everyone. I must admit that this line of thought would not have occurred to me.

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TABLE I.

CORRELATION COEFFICIENTS OF LINEAR AND EXPONENTIAL CURVE FITTINGS TO THE EXPERIMENTAL GROWTH RATE DATA

	Increase in bacteria versus time	
	Linear	Exponential
Irradiated fillets	0.869	0.929
Unirradiated fillets	0.990	0.926

I bring up these arguments to indicate that the consuming public would derive no tangible benefit from food irradiation, but would bear all the potential risk related to the ultimate safety of this food. The food merchants and public health officers, the primary advocates of food irradiation, bear no risk other than as consumers themselves, and gain the benefits of extended storage time, and the public perception that government is doing something to protect the food supply. Should not the potential risk of an innovation be borne by the same groups that derive the benefits? Because of the understandable public aversion to things relating to radiation, some public health officials have proposed that the term *cold pasteurization*[6] be used for food irradiation, an oxymoron when one considers that pasteurization implies heating.

Let us then examine the refereed scientific literature for clues about any potential risks to health from consumption of irradiated food. Unfortunately, proponents of food irradiation have published their studies primarily in consensus reports, internal memoranda, and the like, which are not readily available to the practicing scientist, and I am no doubt unaware of the existence of many of these studies.

Irradiation with high-energy beams splits chemical bonds in molecules to form free radicals and ions. When sufficient critical bonds are broken in organisms contaminating the food, the organisms are killed. Similar bonds are broken within the food. Free radicals contain an unpaired electron and will continue to react with stable molecules to form another free radical and another stable molecule after the radiation is turned off. This process will stop only when two free radicals react to form a stable molecule without unpaired electrons. The lower the dose of radiation, the fewer free radicals are formed and the longer it will take for two free radicals to find each other and collide to terminate these reactions. Different doses of radiation will therefore not only produce different amounts of new molecules, but different kinds as well. This has indeed been documented[7] in actual practice with irradiated fish. As a model for these reactions, I have alluded to the mass spectrum of a pure compound.[8] Here, a high-energy beam is focused on a pure compound and the resulting fragments are separated as a function of charge and mass. The pattern obtained is unique for any pure compound and will identify it unequivocally. In a complex mixture such as a food, this identification of all the constituents is technically not feasible because of their huge number and low concentration, but serves to illustrate that a very large number of new compounds is inevitable. The following example will illustrate the magnitude of new molecules formed during irradiation. It can be calculated that at a dose of 100 krad, 6 of 10 million chemical bonds are broken. This seems like a small number. If one considers the irradiation of water, which constitutes about 80% of many foods, it can be shown that for 100 mL, i.e., 5 g mole, there are a trillion trillion molecules. If 6 of 10 million bonds are broken, then in 100 mL water, one billion billion bonds will be broken. Thus, a very large number of new molecules may be expected to be introduced into food during irradiation with 100 krad. One of these, meta-hydroxyphenylalanine, has been proposed to monitor whether food had been irradiated. These theoretical considerations have been confirmed by looking at the products of irradiation of 280 g pure sucrose as a 2% aqueous solution.[9] In addition to the recovery of 263 g unchanged sucrose, 476 mg of a white crystalline compound, identified as sodium formate, was found, and about 1 g crude yellow syrup, which was not resolved into pure compounds or identified. The formate suppressed the growth of cultured cells and produced chromosomal aberrations.[10] I bring this up to emphasize and document that irradiation should not be considered to be a process,[11] as advocated by proponents of food irradiation, but a means of adding a large number of new compounds to foods, as ruled by the FDA. The identification of all these compounds has not been attempted for technical reasons, but the formation from 1 mole sugar of almost 0.01 mole formate, no doubt derived from formaldehyde, a known mutagen,[12] must give pause to anyone attempting to advocate irradiation as safe. The mutagenicity of formaldehyde has been documented with the Ames Test, which shows 0.05 mg as clearly mutagenic.[13] Higher doses are toxic, as expected. From this experiment, it is evident that irradiation of 30 mg sucrose (1/250 of a teaspoon) will result in a mutagenic dose of formaldehyde. Although small amounts of formaldehyde are present in some foods, increasing its concentration by irradiation will increase the mutagenic burden and increase the incidence of neoplasia over and above what is now seen in population surveys. Thus, unique or ubiquitous, at least one harmful radiolytic product is produced during the irradiation of sugar.

A discussion of a study of irradiation of foods that contain unsaturated fats is timely because the American public is being advised to reduce fat intake, particularly saturated fats, in view of the high correlation between fat intake and cardiovascular disease and several forms of cancer. Irradiation of polyunsaturated fats produces peroxides, which oxidize benzopyrenes in the food to benzopyrene quinones[14] in a dose-dependent manner. The carcinogenicity of these quinones has been documented, and is so potent that these compounds have been used to induce tumors in experimental animals. Unsaturated fats such as cod liver or mackerel oil showed greater quinone formation than saturated fats such as coconut oil or fats containing tocopherol (vitamin E), such as corn oil. The direct relation between quinone formation and peroxide content was documented with irradiation of herring flesh. Peroxidation of lipids results in their polymerization by cross-link formation. We are unable to digest these polymers, with the result that they will be deposited as insoluble plaques in blood vessels, akin to the deposition of insoluble cholesterol plaques, well known to lead to high blood pressure and cardiovascular disease. In a consensus statement frequently quoted to document the safety of irradiated food by its proponents,[15] the following is stated on page 17: "In this research, several anomalies appeared in the test animals (for example, hemorrhages, ruptured hearts, and vitamin deficiencies), but these were related to feeding the test animals food they did not customarily eat, and not to treating the foods with ionizing energy." Hemorrhages and ruptured hearts suggest acute elevation of blood pressure. Should a study be performed that involves feeding animals food they do not customarily eat, and then attribute adverse effects to this, rather than to the nature of the food that was eaten? This reasoning would not be acceptable in the refereed scientific literature. However, these observations illustrate acute effects of irradiated fat-containing foods; induction and detection of neoplasia would take much longer than the duration of this study. Another statement (page 18 of ref. 15) I find unacceptable in this publication is that "... when many experiments are conducted, an occasional statistically significant negative (and positive) outcome is to be expected, even in the absence of any real effect." I bring this up to illustrate the inherent danger of relying, as did the FDA, on studies not peer-reviewed by anonymous referees.

I would next mention the effects of irradiation on foods cured with nitrate (bacon, cold cuts, etc.). Irradiation converts nitrate to nitrite in a dose-dependent manner,[16] and mutagenesis was found to be directly proportional to the nitrite concentration. Nitrite reacts with nucleic acids and various amino acids in proteins to form the recognized family of carcinogens known as nitrosamines. These are unequivocal and potent carcinogens in humans and have been used to induce tumors in experimental animals.

I would now like to turn to the most convincing and comprehensive group of studies to demonstrate the mutagenic effects of irradiated food. Some of these studies were performed in humans. In 1975 the results of feeding five malnourished Indian children wheat irradiated with 75 krad were reported.[17] This wheat produced weight gain, and serum albumin and hemoglobin blood levels indistinguishable from what was found with unirradiated wheat. Food irradiation proponents might have used this part of the study to document the lack of adverse effects of irradiated wheat consumption. However, four of the five children showed gross chromosomal polyploidy 4 wk after initiation of the feeding program. Chromosome number returned to normal 26 weeks after feeding of irradiated wheat ended. This unequivocal evidence of mutagenesis in 80% of the test subjects can be contrasted with the highest cancer incidence in humans, lung cancer, of 80 per 100 000, or 0.08%. No statistical analysis is needed here! My one question would be what was different about the one child who showed no polyploidy. Based on lung cancer incidence, I would have predicted no observable polyploidy increase from a carcinogenic event unless at least 10 000 subjects were tested. Proponents of food irradiation have attempted to dismiss this study because only five subjects were involved; mercifully, no one has repeated this with greater numbers of children, considering that equivalent results were obtained when irradiated wheat was fed to monkeys[18] and rats.[19] In both of these studies, polyploidy was seen after several weeks of feeding and returned to normal about 2 mo after feeding irradiated wheat ended. During hearings before the US Congress, proponents of food irradiation referred to an abstract of a presentation of a Chinese study involving 382 medical students, which showed no statistically significant effects of irradiated food on chromosome number.[20] Some irradiated foods, such as rice and potatoes, even reduced the number of polyploid cells! The most serious criticism of this study is that polyploidy was seen in 0–0.66% of the control subjects and in 0–1.03% of the experimental subjects. In several published studies of young children, not a single case of polyploidy was seen in 14,809 individuals.[21–23] The Chinese findings of polyploidy suggest an inherent background of mutagenic stimulation in this population. This study has not been published in a refereed journal, certainly not in the American Journal of Clinical Nutrition, where the original findings were presented.[17] This would be the accepted procedure for refuting a published study, and the editors of this prestigious journal would not have declined to publish reasonable data to set the record straight.

Let us now consider some of the studies that convinced the FDA to approve food irradiated with as much as 100 krad for human consumption. The criterion used by the FDA is safety of foods or drugs in terms of acute toxicity during short periods of exposure, i.e., months or a few years at most. I have already quoted from a publication[15] that summarizes a series of studies. Weanling rats were fed irradiated food for 8 wk and showed decreased growth rates, which were not considered serious indications of toxicity. In another study, 41 young male volunteers were given irradiated food for 15 days without showing any unfavorable effects. Rats, mice, and dogs were fed irradiated food for 2 y or four generations and showed the previously cited hemorrhages and ruptured hearts, which were attributed to the fact that the animals ate food to which they were not accustomed and not to the fact that the food was irradiated. The details of these studies were not provided, and the manuscript was not reviewed by anonymous referees with competence in this field. However, all the studies were of much too short duration to demonstrate carcinogenicity of irradiated food; this takes several decades. Consider our acceptance of smoking as causing lung cancer. Smokers usually begin smoking in their teens, and do not develop lung cancer until their late forties at the earliest, and usually in their sixties and seventies, i.e., periods of three to six decades. It is surprising that even a few instances of acute toxicity were observed. As shown by the Ames Test with formaldehyde,[12,13] about 0.05 mg were mutagenic and levels >0.07 mg were toxic and killed the cells. Dead cells do not become neoplastic. However, lower levels, which can cause changes in the DNA without killing the cells, require decades to produce clinical cancer in humans. The life span of experimental animals is too short to demonstrate this, and exposing several generations to the agent is not equivalent to several decades of exposure to, for example, cigarette smoke. None of the studies cited previously could have demonstrated the carcinogenicity of cigarette smoke.

Proponents of food irradiation have stated that no unique chemicals (radiolytic products) are introduced into food by irradiation. We do not know whether this is true because a biologic assay suitable to guide the purification of small amounts of materials introduced into the food by irradiation is not available. Nevertheless, unique or ubiquitous, an increase in concentration of a mutagen in food by irradiation will increase the incidence of cancer over and above what is presently observed during several decades of exposure. Formaldehyde and benzo(a)pyrene quinone are clearly increased in concentration by irradiation. If we knew nothing else, this suffices to advise against the consumption of irradiated food.

If consumption of irradiated food were to become widespread, it would take four to five decades to show statistically significant increases in cancer incidence. To recall again the parallel with smoking, the causation of lung cancer by smoking was first realized in the 1960s in the Surgeon General's report. Four decades later, the courts are still involved in this; only recently, tobacco company executives stated under oath before Congress that nicotine in cigarette smoke was not addictive. Even if all smoking ceased today, there are enough past smokers in the pipelines to keep lung cancer at the top of human cancer incidence. Likewise, with food irradiation. It will take four to six decades to demonstrate a statistically significant increase in cancer due to mutagens introduced into the food by irradiation. It will take years to convince the public and combat denials from a by then well-entrenched irradiation industry. When food irradiation is finally prohibited, several decades worth of people with increased cancer incidence will be in the pipelines. This will therefore be an experiment of a century's duration! Is this worth the benefits irradiation will provide for the food industry? As shown previously, irradiation will not eliminate all the contaminating microorganisms; it will only delay the onset of symptoms and will not affect severity and duration of illness.

The effective remedy is to cook food, especially ground beef, adequately (to 170°), not permit raw meat to come into contact with food that will be consumed uncooked, and to thoroughly wash all food that will be eaten raw. Keep in mind that excrement from infected cows could come into contact with produce in the field. However, the long-term consequences of irradiation will be far worse than any disease against which it may have been directed.

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Enrichment of Food Staples Through Plant Breeding: A New Strategy for Fighting Micronutrient Malnutrition

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Can commonly eaten food-staple crops be developed that fortify their seeds with essential minerals and vitamins? Can farmers be induced to grow such varieties? If so, would this result in a significant improvement in human nutrition at a lower cost than existing nutrition interventions? Having concluded that the available scientific evidence indicates positive answers to all three of these questions, an interdisciplinary, international effort is underway to breed for mineral- and vitamin-dense varieties of rice, wheat, maize, beans, and cassava for release to farmers in developing countries. Not only does plant breeding hold great promise for making a significant, low-cost, and sustainable contribution to reducing micronutrient, particularly mineral, deficiencies in humans, it also may well have important spinoff effects for increasing farm productivity in developing countries in an environmentally beneficial way.

Mineral-packed seeds sell themselves to farmers because, as recent research has shown, these trace minerals are essential in helping plants resist disease and other environmental stresses. More seedlings survive and initial growth is more rapid. Ultimately, yields are higher, particularly in trace-mineral–"deficient" soils in arid regions. Because roots extend more deeply into the soil and thus can tap more subsoil moisture and nutrients, the mineral-efficient varieties are more drought resistant and thus require less irrigation. And because of their more efficient uptake of existing trace minerals, these varieties require fewer chemical inputs. Thus, the new seeds can be expected to be environmentally beneficial as well.

After the onetime investment is made to develop seeds that fortify themselves, recurrent costs are low. No behavioral change on the part of consumers is required. Indeed, the strategy seeks to take advantage of the consistent daily consumption of large amounts of food staples by all family members, including women and children who are most at risk for micronutrient malnutrition. Moreover, as a consequence of the predominance of food staples in the diets of the poor, this strategy implicitly targets low-income households.

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THE SERIOUS PROBLEM OF MICRONUTRIENT MALNUTRITION IN DEVELOPING COUNTRIES

It has been estimated that more than 3 billion people in developing countries are deficient in iron.[1] The problem for women and children is more severe because of their greater physiologic need for iron. In poor countries, more than half of pregnant women and more than 40% of non-pregnant women and preschool children are anemic. Iron deficiencies during childhood and adolescence impair physical growth, mental development, and learning capacity. In adults, iron deficiency reduces the capacity to perform physical labor. Iron deficiency is a leading cause of death among women during childbirth.

Globally, approximately 3 million preschool age children have visible eye damage due to a vitamin-A deficiency. Every year, an estimated 250 000 to 500 000 preschool children go blind from this deficiency, and approximately two-thirds of these children die within months of going blind. Estimates of the subclinical prevalence of vitamin-A deficiency range between 100 and 250 million. A number of clinical trials in developing countries have shown that vitamin-A capsule distribution can reduce mortality rates among preschool children on the order of 30%.

Iodine deficiency is the greatest single cause of preventable brain damage and mental retardation in the world. More than 2 billion people in the world live in iodine-deficient environments. Deficiencies

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